REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Claim 22 has been amended to point out that the purified marigold oleoresin obtained by the method described in claim 15 or 16 is a liquid or a paste at room temperature and has a viscosity of not more than 20,000 mPa.s at 30°C. Support is found in the specification at page 10, lines 5-10.

New claim 28 is also presented for additional patent protection.

Turning to the Official Action, claims 22-27 are rejected under 35 USC 102(e) as anticipated by Kumar. This ground of rejection is respectfully traversed as applied to the amended claims.

Claim 22 as amended is directed to a purified marigold oleoresin obtained by the method described in claim 15 or 16, which is a liquid or a paste at room temperature, and has a viscosity of not more than 20,000 mPa.s at 30°C.

On the other hand, Kumar discloses a xanthophylls ester concentrate enriched with trans-lutein esters and a preparation process thereof.

In the preparation process, aliphatic ketonic solvents are used to obtain the object concentrate enriched with trans-lutein esters. The preparation process is as described below (c.f. Kumar column 5, lines 27-48) .

A process for the preparation of the xanthophyll ester concentrate which comprises:

(a) admixing an extract or oleoresin containing xanthophyll esters containing lutein and zeaxanthin fatty acid esters with an aliphatic ketonic solvent selected from the group of 2-propanone, 2-butanone, 2-pentanone, or mixtures thereof at a temperature in the range of 10°C to 30°C, and agitating the mixture by stirring to selectively solubilize the non-xanthophyll ester impurities and the cis-lutein esters and lipids present therein and simultaneously enriching the trans-lutein esters content of the resulting mixture;

(b) filtering the resulting mixture to obtain a trans-lutein enriched xanthophyll esters concentrate in a solid form;

(c) drying the concentrate under a vacuum at room temperature; and

(d) preserving the concentrate at a temperature below 20°C in an inert atmosphere and in airtight opaque containers to prevent degradation of the concentrate.

Further, for example, Kumar describes in Example 1 (column 7, lines 16-30) that "A weighted quantity of marigold oleoresin (180g) with a xanthophyll ester content of 21.80% by weight and showing trans-lutein, cis-lutein and zeaxanthin area percentages, by HPLC, of 64.24, 23.46 and 4.16, respectively, was transferred into an Erlenmeyer flask (1000m1) followed by the addition of 720 ml of 2-propanone. This was stirred using a thermostatically controlled stirrer at 15°C to 25°C for a period of 5-10 hours. After an interval of every 2 hours, a sample was drawn, filtered and the dried precipitated material was analyzed for the ester content and the trans-: cis-ratio by HPLC. Finally, when the desired degree of purity had been achieved the solution containing the precipitate was filtered through a Buchner funnel and the precipitate was dried in a vacuum drier at ambient temperature".

As is clear from the disclosures above, the reference concentrate is a solid at ambient temperature (about 15 to 25°C).

On the other hand, the purified marigold oleoresin obtained by the method of the present invention is a liquid or a paste having a low viscosity at room temperature of not more than 20,000 mPa.s at 30°C, as is clear from the disclosure on page 10, lines 5-7 in the specification.

Thus, the concentrate obtained by the method of Kumar and the purified marigold oleoresin obtained by the method of the present invention are clearly different.

In addition, the step of "dissolving marigold oleoresin in ketone solvent to obtain a solution, and cooling the solution to form precipitates, and removing the precipitates from the solution, and concentrating the solution to obtain the concentrate" in the method of the present invention is the exact opposite from the step of "filtering the resulting mixture to obtain a trans-lutein enriched xanthophyll esters concentrate in a solid form" in Kumar. Accordingly it is impossible that the resulting product is identical or the same.

For the foregoing reasons, the Examiner' s rejection under 35 U. S .C. 102 is clearly overcome.

Claims 22-27 are further rejected under 35 USC 103 as unpatentable over Kumar in view of Sakato. This ground of rejection is respectfully traversed.

As mentioned above, the concentrate obtained by the method of Kumar is solid at ambient temperature (about 15 to 25°C) and hence is clearly different from the claimed purified marigold oleoresin.

Even if according to the disclosure in Sakato, a hydrophilic solvent such as ethanol is added to the solid concentrate in Kumar for filling in a soft capsule, and as a result, an oily substance having low viscosity is obtained for the content of the capsule, there is still no relation between such combination and the present invention. This is because the purified marigold oleoresin obtained in the present invention is a liquid or a paste having a low viscosity at room temperature, and therefore it can be filled in a soft capsule using no solvent.

The value of viscosity in the present invention represents the viscosity of the purified marigold oleoresin itself, and it does not represent the viscosity of a solution containing the purified marigold oleoresin in an oily substance and/or an organic solvent.

Thus, in the present invention, no solvent to solubilize a solid as in Sakato is necessary. In this point, the present invention is advantageous over Sakato.

For the foregoing reasons, the Examiner's rejection under 35 U.S.C. 103(a) is clearly overcome.

Furthermore, it is respectfully submitted that the rejection is untenable if applied to new claim 28. New claim 28 is directed to a composition consisting essentially of purified marigold oleoresin obtained by the method described in claim 15 or 16, which is a liquid or a paste at room temperature, and has a viscosity of not more than 20,000 mPa.s at 30°C. It is well recognized that the claim preamble "consisting essentially of" is open claim language which excludes any ingredient from the composite which would effect the basic and novel properties of the claimed composition. It is respectfully submitted that the claim preamble "consisting essentially of" appearing in claim 28 excludes the presence of a solvent from the purified marigold oleoresin of the present invention, because it would effect the basic and novel properties of the purified marigold oleoresin of this invention. As discussed above, the purified marigold oleoresin obtained by the present invention has a low viscosity itself and can be filled in a soft capsule using no solvent. The present invention is advantageous over Sakato because a solvent is

unnecessary and would be undesirable in making soft capsules of purified marigold oleoresin.

Thus it is respectfully submitted that claim 28 is patentable over Kumar and Sakato.

Claims 15, 17-22/15 and 27/15 are rejected under 35 USC 103 as unpatentable over Madhavi et al. in view of Kanel et al., Rao et al. and Kumar. This ground of rejection is respectfully traversed.

The essential features of the method of the present invention (claim 15), and the difference between the methods of the present invention and the cited prior art are set forth below and in the attached comparison tables between the present invention and the cited prior art.

Essential features of the method of the present invention (claim 15)

A method for producing purified marigold oleoresin of the present invention is characterized by a combination of (1) a 1st step of supercritical fluid extraction of marigold oleoresin, to obtain an extraction residue, and to remove the extraction solution, (2) a 2nd step of dissolving the extraction residue of marigold oleoresin in a ketone solvent to obtain a solution, and (3) a 3rd step of removal of the ingredient which precipitates in solution by cooling, and concentrating the solution to obtain the desired purified marigold oleoresin (c.f. Comparison Tables).

Madhavi et al.

Madhavi et al. discloses a method of recovering a crystalline precipitate of a lutein enriched mixed carotenoid product involving a step of hydrolyzing marigold oleoresin with excess aqueous saponification agent. Please see claim 1 and the disclosure on column 2, lines 29-37.

Accordingly the process of producing the carotenoid product, and the product obtained in Madhavi et al., are quite different from those in the present invention.

Please note that Madhavi et al. neither describes nor suggests essential features (1) to (3) of claim 15.

Therefore, even if Madhavi et al. is combined with any other cited reference, the method of producing in the present invention cannot be obvious to a person skilled in the

art, and the desired purified marigold oleoresin in the present invention cannot be obtained.

Kanel et al.

Kanel et al. discloses merely that supercritical carbon dioxide is preferable in the supercritical fluid extraction, and an organic solvent such as acetone is usable as a co-solvent .

It is quite clear that essential features (1) to (3) of claim 15 are not described nor suggested in the cited Kanel et al.

Rao et al.

Rao et al. discloses a process for the extraction by the supercritical fluid carbon dioxide of the lutein diester from the milled marigold meal. That is, the milled marigold meal is dissolved in supercritical fluid carbon dioxide in the first extractor apparatus, so that lutein diester and lipophilic materials of the milled marigold meal are dissolved in the supercritical fluid carbon dioxide.

However, Rao et al. neither discloses nor suggests the extraction of marigold oleoresin as in the present invention by supercritical fluid carbon dioxide.

Further, in Rao et al., the desired lutein diester of the milled marigold meal is dissolved in the supercritical fluid carbon dioxide. On the other hand, in the present invention, the desired marigold oleoresin is not dissolved in the supercritical fluid carbon dioxide, but is present in the extraction residue.

In other words, Rao et al. teaches purifying the extraction solution, whereas in the present invention, the extraction residue is purified. Thus even if Rao et al. and Kanel et al. are combined with Madhavi et al., the claimed method is not suggested.

Furthermore, Rao et al. does not describe nor suggest the 2nd step of dissolving the extraction residue of marigold oleoresin in a ketone solvent to obtain the solution, and the 3rd step of removal of the ingredient which precipitates in solution by cooling.

Thus, the extraction of marigold oleoresin by supercritical fluid carbon dioxide to obtain the extraction residue as well as essential features (1) to (3) of claim 15 are not described nor suggested in Rao et al.

Kumar

As mentioned above and is clear from Comparison Table, the process of Kumar is the exact opposite from that of the present invention. Kumar does not describe nor suggest essential features (1) to (3) of claim 15, even taken with Madhavi et al., Rao et al. and Kanel et al.

For the foregoing reasons, the Examiner' s rejection under 35 U.S.C. 103(a) is clearly overcome.

Lastly, claims 23-26/15 are rejected under 35 USC 103 as unpatentable over Madhavi et al. in view of Kanel et al., Rao et al., Kumar and Sakato. This ground of rejection is also respectfully traversed.

As explained above, the process of Kumar et al. is exactly opposite from the method of the present invention. Therefore, the concentrate obtained in Kumar et al. is quite different from the purified marigold oleoresin obtained by the method of claim 15.

Sakato et al. describes a process of producing capsules comprising adding into an oily substance a hydrophilic solvent, e.g. ethanol which dissolves therein to lower the viscosity and enclosing them in a capsule.

However, this technique is not related to the present invention at all.

Rao et al. describes a process for the extraction by the supercritical fluid carbon dioxide of the lutein diester from the milled marigold meal, followed by fractionating and isolating the lutein diester extract at a specific pressure range and a specific temperature range, whereby to obtain the lutein diester deodorized and containing reduced volatile materials and saturated fats.

However, Rao et al. neither discloses nor suggests the extraction of marigold oleoresin by supercritical fluid carbon dioxide anywhere.

As is clear from the above explanation, all of Rao et al., Kumar and Sakato patents do not disclose the technique which is relevant to the present invention. Therefore, these references are not pertinent prior art against the present invention.

Besides, Madhavi et al. discloses a method of recovering a crystalline precipitate of a lutein enriched mixed carotenoid product involving hydrolyzing maligold oleoresin with excess aqueous saponification agent (column 3, line 43).

Thus, the process of producing and the product obtained are quite different from those of the present invention.

Therefore, even if Madhavi et al. is combined with the other cited references, the method of producing in claim 15 cannot be suggested to a person skilled in the art, and the purified marigold oleoresin obtained by the method of claim 15 cannot be obtained.

Kanel et al. describes merely that supercritical carbon dioxide is preferable in the supercritical fluid extraction, and an organic solvent such as acetone is usable as co-solvent.

For the foregoing reasons, the Examiner' s rejection under 35 U.S.C. 103 is clearly overcome.

In view of the foregoing, it is respectfully submitted that each ground of rejection set forth has been overcome by the foregoing arguments and amendments.

Accordingly, reconsideration and allowance is solicited.

Respectfully submitted,

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	The present invention Claim 15	Description	Medhavi et al. USP 6,380,442
	A method for producing purified marigold oleoresin, which comprises:		A method for producing a lutein enriched mixed cartenoid product from a lutein ester source, comprising the steps of (a) to (e) (claim 1)
1st Step	subjecting marigold oleoresin to supercritical fluid extraction, to obtain an extraction solution and an extraction residue;	The components extracted by carbon dioxide in the supercritical state are recovered by evaporating carbon dioxide while decreasing the pressure in a separator vessel and is removed.(page 8, lines 6 to 11)	No mention
			commercially available food frade marigold oleoresin produced by hexane extraction can be used the starting material for the isolation of all trans lutein enriched product. (column 3, lines 2 to 5) The process can be used to recover the carotenoids from·····oleoresins obtained by supercritical extraction. (column 2, lines 38 to 41)
2nd Step	dissolving the extraction residue in a ketone solvent to obtain a solution;	dissolving the extract residue of marigold oleoresin (Examples 1 and 2) dissolving marigold oleoresin (Example 3)	No mention
3rd Step	cooling the solution to form precipitates and removing the precipitates from the solution; and concentrating the solution, to thereby obtain the purified marigold oleoresin.		No mention
		(a) dissolving the lutein ester source in isopropanol solvent at a temperature ranging from about 60 to 65 ℃ to form a free-flowing solution of carotenoids; (b) hydrolyzing said dissolved lutein ester source with excess aqueous saponification agent; (c) cooling said hydrolyzed solution to about ambient temperature; (d) adding aqueous solvent to said cooled solution to precipitate a carotenoid product; (e) recovering said precipitated carotenoid product.	

	The present invention Claim 15	Kanel et al. USP 5,932,101
	A method for producing purified marigold oleoresin, which comprises:	No mention
		This invention relates to fluid extraction and more particularly to the extraction of solutes utilizing a dense gas under enhanced solubility conditions. (column 1, lines 11 to 13)
1st Step	subjecting marigold oleoresin to supercritical fluid extraction to obtain an extraction solution and an extraction residue;	No mention
		This invention is a process for extracting a solute(s) from a fluid feed by intimately contacting the fluid feed with a extraction solvent ····· in an enhanced solubility region. (column 4, lines 62 to 65) The fluid feed may also be in the form of a slurry ·····. Examples of the dispersed solid phase include ·····ground plant matter, ····· ground seeds,····· . (column 5, lines 41 to 46, 48) The dense gas ····· is preferably supercritical carbon dioxide. (column 6, lines 5 to 6) The dense gas may contain ·····co-solvents·····. The examples include ·····, ethanol, acetone, tetrahydrofuran, ·····. (column 6, lines 12 to 15)
2nd Step	dissolving the extraction residue in a ketone solvent to obtain a solution;	No mention
3rd Step	cooling the solution to form precipitates and removing the precipitates from the solution, and concentrating the solution, to thereby obtain the purified marigold oleoresin	No mention

	The present invention Claim 15	Sakato US 5,288,550	Rao US 2004/267033 A1
	A method for producing purified marigold oleoresin, which comprises:	No mention	The present invention is directed to a process for the extraction of lutein diester from marigold meal. [0025]
	subjecting marigold oleoresin		No mention
	to supercritical fluid extraction, to obtain an extraction solution	No mention	The marigold meal particles are fluidized in a mass carbon dioxide flow ranging from 20-80kgm/kgm of dry marigold meal to form a process steam. The milled meal is dissolved in supercritical fluid carbon dioxide in the first extractor apparatus, so that lutein diester and lipophilic materials of the milled marigold meal are dissolved in the supercrtitical fluid carbon dioxide. [0025]
1st Step	and an extraction residue;		No mention
2nd Step	dissolving the extraction residue in a ketone solvent to obtain a solution;	No mention	No mention
3rd Step	cooling the solution to form precipitates and removing the precipitates from the solution; and concentrating the solution, to thereby obtain the purified marigold oleoresin.	No mention	No mention
		A production method of a non-fitting type capsule according to the present invention comprises adding into an oily substance a hydrophilic solvent which dissolves therein and enclosing them in a capsule. (column 2, lines 22-25)	

	The present invention Claim 15	Kumar US 6,737,535 B2
	A method for producing purified marigold oleoresin, which comprises:	··· is provided a process for the preparation of the above defined xanthophyll ester concentrate which comprises; (column 5, lines 28 to 30)
1st Step	subjecting marigold oleoresin to supercritical fluid extraction, to obtain an extraction solution and	the commercially produced food grade marigold oleoresin using hexane as an extractant can be used as the starting material for the process of the present invention. (column 6, lines 6 to 8)
	an extraction residue;	No mention
		(a) admixing an extract or oleoresin containing xanthophyll esters containing lutein and zeaxanthin fatty acid esters with an aliphatic ketonic solvent selected from the group of 2-propanone, 2-butanone, 2-pentanone, or mixtures thereof, at a temperature in the range of 10℃. and 30℃. (column 5, lines 31 to 36)
2nd Step	dissolving the extraction residue in a ketone solvent to obtain a solution;	No mention
3rd Step	cooling the solution to form precipitates and removing the precipitates from the solution; and concentrating the solution, to thereby obtain the purified marigold oleoresin.	No mention
		and agitating the mixture by stirring to selectively solubilize the non-xanthophyll ester impurities and the cis-lutein esters and lipids present therein and simultaneously enriching the trans-lutein esters content of the resulting mixture;
		(b) filtering the resulting mixture to obtain a trans-lutein enriched xanthophyll esters concentrate in a solid form;
		(c) drying the concentrate under a vaccum at room temperature; (column 5, lines 36 to 45) so as to remove the impurities and as well as to precipitate the trans-lutein esters enriched xanthophyll esters, followed by filtration and washing with the same solvent. (column 6, lines 23 to 26)